DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 27 1999

NADA 141-107

William Davis, MD
ALACO, Inc
1500 N. Wilmot Road
Suite 290C
Tucson, AZ 85712

Dear Dr. Davis:

We refer to your promotional piece, coded B1 4332-5 4/98 for Bapten, NADA 141-107. The material was collected under our Surveillance at Professional Meetings Program from the Eastern States Veterinary Conference held on January 9-13, in Orlando, Florida. As stated in the promotional literature, the indication for Bapten is "For the treatment of tendinitis of the superficial digital flexor tendon (SDFT) in the adult horse where there is sonographic evidence of fiber tearing." On the first page of the promotional literature under "Benefits" it states that "Results in a more athletically functional repaired tendon" and under "Advantages", it states that "Bapten is the only FDA-approved scar remodeling agent that improves the repair quality of injured tendons to pre-injury performance, when combined with an appropriate exercise program." While Bapten may be the only FDA-approved scar remolding agent, there is no data in the NADA to support the claim that Bapten improves the repair quality of injured tendons to pre-injury performance, when combined with an appropriate exercise program" and "Results in a more athletically functional tendon." These two statements are not consistent with the approved claim under "Indication". As such, the promotional piece in question causes your product to be misbranded under Section 502(a) of the Act.

We wish to remind you of the commitment you made when you signed the New Animal Drug Application Form, FDA-356V, that you will promote your product only in accordance with the labeling provided for in the approved application. We request that you discontinue using this promotional piece and in the future promote your product only in accord with the approved labelig.

Under 21 CFR 510.300(b)(2)(I) you are required to submit information concerning any unexpected side effect, injury, toxicity or sensitivity reaction in a special drug experience report within 15 working days of its receipt by the sponsor. We also request that you submit recent adverse reaction reports that caused you to voluntarily withdraw you product from the market, if you have not done so already..

Please inform us of your intentions as soon as possible, or in any event within 30 days of receipt of this letter. If you have any questions, you may contact us at (301) 827-6642.

Sincerely

/S/

Mohammad I. Sharar, DVM, MSc.
Team Leader, Marketed Product Scientific
And Regulatory Review Team II, HFV-216
Division of Epidemiology and Surveillance
Center for Veterinary Medicine